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### Bridgeport, C1 06003-1601 5734	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
R Neil Sudol EXAMINER	10/517,032	12/07/2004	Sergio Capurro	BA-22902	2851
Coleman Sudol Sapone PC	R Neil Sudol Coleman Sudol Sapone PC			EXAMINER	
Bridgeport, CT 06605-1601 ART UNIT PAPER NUMBEL 3734 MAIL DATE DELIVERY MOE				YABUT, DIANE D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/517.032 CAPURRO, SERGIO Office Action Summary Art Unit Examiner DIANE YABUT 3734 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 28 November 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-13 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-13 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SZ/UE)
Paper No(s)/Mail Date ______

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application.

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DETAILED ACTION

This action is in response to applicant's amendment received on 11/28/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "or other solidifying material suited to the purpose" renders the claim indefinite because the claim includes elements not actually disclosed, thereby rendering the scope of the claim unascertainable.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scirica et al. (U.S. Patent No. 5,908,428) in view of Villegas (U.S. Patent No. 2,581,564).

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Claims 1-6: Scirica et al. disclose a surgical needle having two tissue penetrating and beveled needle tips 204, 208 and comprising a cylindrical shaft, the shaft having a central portion that is equipped with a hole 212 on one wall of the hollow shaft through which emerges a surgical thread 34 that is anchored inside the needle (Figures 5-7). One end of the surgical thread 34 is inserted into the hole 212 of the needle and is anchored by pinching the needle (col. 10, lines 21-26).

Scirica et al. disclose the claimed device except for the shaft being an atraumatic metallic needle being hollow from tip to tip and the external surface being cylindrical from tip to tip.

Villegas teaches a wholly tubular or cylindrical and hollow atraumatic and metallic needle 10 (Figures 1-2). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Scirica et al. by having a shaft being hollow from tip to tip, as taught by Villegas, to further anchor the thread and so that the thread may be threaded, unthreaded and sterilized repeatedly within the needle (col. 2, lines 1-4). It also would have been obvious to one having ordinary skill in the art at the time the invention was made to make the needle of Scirica et al. metal, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

<u>Claim 13</u>: Although neither Scirica et al. nor Villegas expressly disclose the surgical thread being fixed by means of two or more anchoring techniques, it would have been obvious to one of ordinary skill in the art to further secure the thread to the needle by

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using more than one anchoring technique, as a person of ordinary skill would recognize that doing so would strengthen the connection between the thread and the needle.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Scirica et al. (U.S. Patent No. 5,908,428) in view of Villegas (U.S. Patent No. 2,581,564), as applied to claim 1 above, and further in view of Coplan (U.S. Patent No. 3,918,455).

Claims 7-11: Scirica et al. and Villegas disclose the claimed device, including an atraumatic surgical needle with one end of the surgical thread being inserted into the hole and being anchored inside the atraumatic two-tipped needle, except for being anchored by means of a scotch, a solid bar or a portion of tube, made of metal or plastic, the caliber of which is determined by the diameter of the needle, which is pushed down inside the needle from one of the two ends.

Coplan teaches a surgical thread, emerging from one end of the needle, being inserted and anchored, or fixed, in a hole in one end of a scotch 34, a solid bar or a portion of tube, made of metal or plastic, the caliber of which is determined by the diameter of the needle, which is pushed down inside the needle from one of the two ends (Figure 4, col. 4, lines 55-63 and col. 6, lines 60-62). Coplan teaches that the use of the scotch 34 for a suture-needle combination reduces trauma at the site of tissue penetration and reduces hazard of suture tear-out (col. 1, lines 60-68). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Scirica et al. and Villegas by providing a scotch, which is pushed down inside the needle from

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one of two ends, as taught by Coplan, in order to reduce trauma at the site of tissue penetration and hazard of suture tear-out.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scirica et al. (U.S. Patent No. 5,908,428) in view of Villegas (U.S. Patent No. 2,581,564), as applied to claim 1 above, and further in view of Borst (U.S. Pub. No. 20040260145). Claim 12: Scirica et al. and Villegas disclose the claimed device, including a surgical thread being inserted into an atraumatic two-tipped needle, except for the thread being fixed between the coils of a tiny spring.

Borst teaches a suture being fixed between the coils of a tiny spring (page 11, paragraph 132). It would have been obvious to one of ordinary skill in the art to fix a suture between the coils of a tiny spring, as taught by Borst, to Scirica et al. and Villegas since it was known in the art that springs are used as flexible retaining means for sutures, threads, and cords.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hayhurst et al. (U.S. Patent No. 5,041,129) discloses a hollow tubular needle 10 with a hole 18 in the central portion (Figure 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734